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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jianbo Xie

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EXAMINER

KARPINSKI, LUKE E

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/31/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,627	<b>Applicant(s)</b> XIE ET AL.	
	<b>Examiner</b> LUKE E. KARPINSKI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,9,10,12-16,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 10, 12-16, 34, and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Receipt of amendments, arguments, and remarks filed 12/30/2008 is acknowledged.

### ***Claims***

Claims 2-8, 11, and 17-33 are canceled.

Claims 1, 9, 10, 12-16, 34, and 35 are currently pending and under consideration in this action.

### ***Rejections***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**1. Claims 1, 9, 10, 12-16, 34, and 35 rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent Publication 2004/0224020 to Schoenhard in view of US Patent 5,160,742 to Mazer et al.

### ***Applicant Claims***

Applicant claims a tablet consisting of:

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a) a core consisting of oxycodone, a diluent, a binder and viscosity thereof, and optional glidants and lubricants,

b) a single delayed release coating consisting of 30-80% pH dependant material, said first material dissolving at pH 5-7 and said second material dissolving at pH above 8, and 20-70% inert processing aid,

c) an immediate release layer comprising oxycodone and a binder.

Applicant further claims different viscosities and pHs, ratios of said pH materials, and percentages of most components.

***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Schoenhard teaches tablets comprising a core and an immediate release coating [0006], a delayed release coating [0116], said core consisting of an active and a controlled release material (binder) [0055], said active as oxycodone [0053], said controlled release material as hydroxypropylmethylcellulose [0058], which reads on a binder [0147] and has a viscosity above 50,000, a diluent, optional glidants and lubricants [0140], said delayed release coating comprising a material which begins to dissolve a pH 5-7 [119-120] (Eudragit L100 and S1000), and a material which begins to dissolve at a pH above 8 [0120] (zein), said coating as tack free [0098], and the utilization of talc as a processing aid to reduce sticking [0064], an immediate release layer comprising oxycodone [0009] and [0029], and a binder [0029] (gelatin), as pertaining to claims 1 and 35.

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Schoenhard further teaches HPMC as a binder, which has a viscosity of 75,000 or greater [0058] and [0147], as claimed in claim 9, a material dissolving at a pH of above 9 and between 11-12 [0119] (zein), as claimed in claim 10 and 12, that the dissolution profile may be altered by altering components and percentages thereof ([0060] [0062] [0065] and [0116-120]), as pertaining to claims 1, 13, 14, 15, 16, and 35, a specific amount of oxycodone to utilize [0053] as pertaining to claims 34 and 35, a percentage of binder to use [0079], as pertaining to claims 34 and 35, and reasons for altering the amount of a diluent [0150], as pertaining to claim 35.

***Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Schoenhard does not teach the specific percentages of the pH dependant material, inert processing aid, or oxycodone as claimed in claims 1, 13-16, 34, and 35. This deficiency in Schoenhard is cured by both the teachings of Schoenhard and Mazer et al. Mazer et al. teach delayed release coatings comprising percentages of processing aids and therefore also pH dependant materials (col. 8) and cores comprising specific percentages of oxycodone and excipients (col. 7).

Schoenhard also does not teach an inert processing aid percentage of 20-70% or 30-60%, as claimed in claims 1, 16, and 35. This deficiency in Schoenhard is cured by Mazer et al. Mazer et al. teach enteric coatings comprising talc present at 30% as an anti-tackiness agent (col. 8).

***Finding of Prima Facie Obviousness Rational and Motivation***  
***(MPEP §2142-2143)***

Regarding the limitations of percentages of said active and said binders within said core, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the tablets of Schoenhard with up to 80% excipients, and therefore 20% active as taught by Mazer et al. in order to produce the invention of instant claims 34 and 35.

One of ordinary skill in the art would have been motivated to do this because Schoenhard and Mazer et al. teach to analogous art, Schoenhard teaches cores comprising oxycodone and a binder and a specific mg weight of active to use and Mazer et al. teach cores comprising up to 80% excipients, such as binders. Therefore it would have been obvious to utilize the up to 20% active and up to 80% binder of Mazer et al., in the tablet formulations of Schoenhard in order to produce tablet cores with known and accepted active to binder percentages.

Regarding the limitations of percentages and ratios of said pH dependant materials, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the tablets of Schoenhard with the pH dependant materials, ratios of, and percentages thereof as taught by Mazer et al. and Schoenhard in order to produce the invention of instant claims 1, 13-16, and 35.

One of ordinary skill in the art would have been motivated to do this because both Schoenhard and Mazer et al. teach tablets which may be coated in a delayed release coating (enteric coating), both references teach agents which may be utilized

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within said coatings which dissolve at pH's of 5-7 and between 11 and 12, and Schoenhard teaches that a desired dissolution rate may be obtained through the utilization of different materials and percentages thereof within said delayed release layer. Therefore it would have been obvious to utilize the pH dependant materials, percentages, and ratios thereof of Mazer et al., in the tablet formulations of Schoenhard in order to produce a tablet which will release said active at a desired rate and also in a desired point in the digestive system.

Regarding the limitations of percentages of inert processing aids, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the tablets of Schoenhard with up to 30% talc as taught by Mazer et al. in order to produce the invention of instant claims 1, 16, and 35.

One of ordinary skill in the art would have been motivated to do this because both Schoenhard and Mazer et al. teach tablets which may be coated in a delayed release coating (enteric coating), both references teach anti-tack agents present and Mazer et al. teach a specific amount of said anti-tack agent (talc). Therefore it would have been obvious to utilize up to 30% talc as taught by Mazer et al., in the tablet formulations of Schoenhard in order to produce a delayed release coating with out tackiness.

Each limitation of the instant invention is either known in the art or known as a result effective parameter. The prior art teaches the general product of a core surrounded by a single delayed release layer, surrounded by an immediate release layer with oxycodone in both the core and the immediate release layer. The prior art



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also teach cores and immediate release layers comprising excipients, including the instantly claimed binders, and the use of said excipients at different percentages has been known for quite some time and would be obvious to one of ordinary skill in the art. The prior art also teaches enteric coatings, which read on the instant delayed release coatings, and said coating made from different known components with known pH dissolution levels, the prior art also teach that it is known to alter these components and percentages to change the dissolution profile and one of ordinary skill would know how to alter said profiles. The one aspect of the instant invention which is not explicitly disclosed or taught in the cited prior art are the specific percentages and pH dependant materials which dissolve at specific pH levels, however this simply results in a different dissolution profile and it is known in the art that said profiles may be altered and one of ordinary skill would readily know how to alter said components to achieve the desired profile, therefore the one aspect of the instant invention which is not explicitly disclosed would have been obvious to one of ordinary skill in the art at the time of the invention.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

***Response to Arguments***

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Claims 2-8, 11, and 17-33 are canceled.

Claims 1, 9, 10, 12-16, 34, and 35 are rejected.

No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

/Mina Haghighatian/  
Primary Examiner, Art Unit 1616